

REMARKS

I. Status of the Claims

Claims 1-18 are pending. No claims have been amended or cancelled by this response.

II. Rejections Under 35 U.S.C. § 103

A. Lim'438 in view of Akram

The Office has maintained the rejection of claims 1-18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent. No. 6,074,438 ("Lim") in view of U.S. Patent No. 5,230,710 ("Akram") for the reasons set forth at pages 2-5 of the Final Office Action. Applicants respectfully traverse the rejection for the reasons of record, as well as for the following additional reasons.

The Office alleges that Lim teaches both the components in the claimed composition are suitable for use together. See Final Office Action, p. 4. The Office further alleges that it is notoriously well known that hair dying compositions may contain several dye bases, and Lim teaches that the two claimed dye bases are suitable for use together in oxidation hair dying compositions¹. *Id.* According to the Office, since Lim teaches that the claimed dye bases are compatible, they have known utility in the same process under the same process conditions. *Id.* Thus, the Office concludes that Lim alone is sufficient to provide a teaching that the two claimed components are useable together in oxidative hair dyeing compositions and processes. *Id.*

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¹ Applicants assume that by "the two claimed dye bases," the Examiner means the claimed base and the claimed coupler. If not, clarification is requested.

However, Applicants respectfully submit that the Office is overstating the teachings of Lim. Contrary to the Office's arguments, Lim does not teach that Applicants' claimed components are necessarily usable or compatible together. Rather, Applicants' claimed components are taught separately as additional ingredients which may be added to Lim's core components, but are not necessarily required. Regarding these additional ingredients, Lim reads as follows:

In addition to at least one of the dye molecules encompassed by the present invention, the hair dyeing compositions described herein may also contain at least one other known and usual dye ingredient . . .

Illustrative component dye ingredients that are conventionally admixed and employed as constituents of customary hair dye formulations and that can be considered suitable for use in the compositions of the present invention are set forth herein below.

See Lim, column 4, line 66 to column 5, line 11. Lim then provides a long list of possible additional ingredients. See Lim, columns 5- 7. Importantly, while this language teaches that the listed ingredients can be considered suitable for use in the compositions of the present invention, it does not state that all of the additional ingredients are compatible for use together. Nor does it follow from the teaching of Lim that any two of the additional ingredients listed are necessarily suitable for use together. Thus, the Office's allegation that Lim alone is sufficient to provide a teaching that Applicants' two specifically claimed components are useable together is simply not supported by the teachings of Lim.

Furthermore, even if, for the sake of argument, Lim did teach that all the additional ingredients were compatible for use with each other, this still would not provide motivation for choosing Applicants' specifically claimed combination from among the multitude of additional ingredients taught by Lim. As the Office is well

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aware, "a proper analysis under § 103 requires, *inter alia*, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition." *[Emphasis added]*. See M.P.E.P. § 2144.08(II)(A). Further, the pyrazolin-5-one couplers (3) and (4) and pyrazole coupler (5) are not part of the present invention. Accordingly, to truly obtain Applicants' composition, one of Lim's core ingredients would have to be excluded. Thus even if all the additional ingredients were suitable for use together, this alone would not provide sufficient motivation to suggest that Applicants' specifically claimed ingredients should be used together.

The Office has additionally argued that the addition of Akram narrows the choice since Akram gives the particular motivation to select 2,6-bis(hydroxyethylamino)toluene from the list of couplers suggested by Lim. See Final Office Action, p. 5. However, art references must be considered in their entirety. See M.P.E.P. § 2141.02. Thus, when considering Akram, the skilled artisan would not only consider the coupler taught by Akram which is read on by Applicants' claims, but also all those couplers taught by Akram which fall outside the scope of Applicants' claims. For this reason, Akram can be seen as expanding the choice of possible couplers.

Even if, for the sake of argument only, Akram would have provided sufficient motivation to choose Applicants' claimed coupler, Akram still fails to provide the missing motivation to choose the presently claimed oxidation base from among the laundry list of additional ingredients disclosed by Lim and combine it with the claimed coupler. In determining the differences between the art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *[Emphasis in*

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original]. See M.P.E.P. § 2141.02. Because neither Lim nor Akram, taken individually, or together, suggest the claimed combination of Applicants' oxidation base and coupler, the claimed invention as a whole would not have been obvious. For at least this reason, the rejection should be withdrawn.

Not only do Lim and Akram fail to provide the necessary teachings to support a *prima facie* case of obviousness, there is evidence in the art, including teachings of both Lim and Akram themselves, to support a conclusion that the hair dye art is generally unpredictable, thus further undercutting the Office's proposed combination of Lim and Akram. Given this general unpredictability, it would not have been obvious to combine the 2,6-bis(hydroxyethylamino)toluene coupler of Akram with the optional p-aminophenols listed in Lim to achieve a workable hair dye composition, let alone to achieve the properties touted by Akram.

This unpredictability is due, in part, to the stringent requirements of oxidative hair dyes. Lim teaches that, "[i]n order for procedures using permanent oxidative dyes to work properly, a number of parameters and conditions are important to consider in the use of the permanent oxidative dye intermediates in admixtures with couplers in hair color preparations for human hair." See Lim, column 1, lines 42-46. Lim then goes on to list various parameters which must be considered, including final color and color intensity after application to the hair; wash fastness and light fastness of the resulting dye; the resistance of the dye to perspiration, as well as to various hair treatments, such as permanent wave, straightening, shampooing, conditioning and rubbing. *Id.* at lines 45-52. Further, "the dye must have virtually no allergenicity or dermal or systemic toxicity." *Id.* at lines 52-53.

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Thus, according to Lim, there are many stringent requirements for oxidative hair dyes which must be considered when combining oxidatation bases and couplers. It is important to note that these teachings of Lim focus on the properties of the resulting dyes, rather than the properties of the oxidation bases and couplers alone. Thus, a reasonable expectation of success may be achieved only to the extent that the skilled artisan could have reasonably predicted that an untried combination of oxidation bases and couplers would achieve these stringent requirements. Predicting such stringent requirements would be difficult at best. Indeed, *Akram* himself admits general unpredictability, referring to the requirements of dyestuffs but pointing out that the requirements cannot always be made to coincide when combining oxidation development components with couplers. See *Akram*, col. 1, lines 13-45.

A well known text in the art supports the view that all of the stringent requirements of hair dyes may not be readily predicted by reference to the properties of the oxidation bases and couplers alone. Rather, dye components can interact to unpredictably affect the properties of the composition, including its toxicity. See C. Zviak, *The Science of Hair Care*, Marcel Dekker, Inc., p. 329 (1986), a copy of which is attached for the Examiner's convenience. Specifically, Zviak explains that, with respect to the safety of finished products, "[a]ll finished cosmetic products must be evaluated for safety in use to make sure that they do not, under normal and foreseeable conditions, constitute a potential hazard for the consumer...." *Id.* According to Zviak, such testing is not easily accomplished due to unpredictable component interactions. Specifically, "[i]t might seem that a sensible way of proceeding would be to conduct most toxicological tests on the ingredients, which would reduce the amount of

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experimentation and cost of developing finished products." However, Zviak notes, "experience has shown that the formulation itself is the important element. It determines local tolerance after a single or repeated application, eye and/ or lung mucosa tolerance, the degree of absorption through the skin, etc." *Id.* Further, according to Zviak, synergistic effects that make a product more or less toxic may occur. That is, "[a]part from the effect of the vehicle, it has been observed that the association of different compounds can produce either synergistic toxicity or, on the contrary, a mitigation or even inhibition of toxic effects." *Id.*

Moreover, Applicants' specification provides additional evidence of unpredictability. Applicant reports in Example 3 on pages 13-18 of the present specification that a composition comprising an oxidation base (para-aminophenol) which does not correspond to formula (I) and the claimed coupler, exhibits increased degradation of color as compared to Examples 4 and 5, which are compositions comprising at least one oxidation base of formula (I) and a coupler, 1,3-bis(β-hydroxyethyl)amino-2-methylbenzene, as recited in the claims.

Thus, given the general unpredictability of the hair dye art, there would have been no reasonable expectation that combining an optional oxidation base randomly chosen from the disclosure of Lim with the coupler of *Akram* would result in compositions having all the properties touted by *Akram*, or that they would even result in a workable hair dye, given the stringent requirements of hair dye compositions. Without some reasonable expectation of success, no *prima facie* case of obviousness has been established, and the rejection should be withdrawn.

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Importantly, all the data and arguments herein are not proffered to rebut a *prima facie* case of obviousness. Instead, as stated above, they demonstrate that the Office has failed to establish a *prima facie* case of obviousness.

B. Lagrange and/or Clausen in view of Zviak and Akram

The Office has maintained the rejection of claims 1-18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,703,266 ("Lagrange") and/or U.S. Patent No. 4,797,130 ("Clausen") in view of Zviak² and Akram, for the reasons set forth at pages 5-8 of the Final Office Action. Applicants respectfully traverse this rejection for the reasons of record, as well as for the additional reasons which follow.

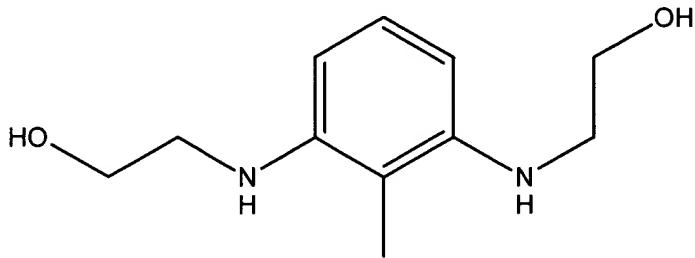
In response to Applicants' remarks filed October 5, 2001, the Office has argued that Applicants' claimed coupler chosen from 1,3-bis(β-hydroxyethyl) amino-2-methylbenzene and the addition salts thereof with an acid is within the scope of the couplers of formula III in column 4 of Lagrange. See Final Office Action, p. 7. The Office has further alleged that Lagrange discloses the mixture as claimed, and accordingly discloses the compatibility of the two claimed components and their use in oxidative hair dyeing compositions and processes. *Id.* Still further, the Office has argued that the rejection does not require one of ordinary skill in the art to ignore the couplers of Lagrange and Clausen because La Grange teaches the coupler as claimed in combination with the developer as claimed. *Id.*

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² Zviak, C. and M. Dekker, The Science of Hair Care, New York (1986) pp. 264-266.

However, contrary to the Office's arguments, Formula III of Lagrange does not encompass Applicants' claimed coupler chosen from 1,3-bis(β-hydroxyethyl) amino-2-methylbenzene and the addition salts thereof with an acid. For example, Formula III requires an -NH₂ group (unsubstituted amino) in the meta position from the -NR₅R₆ group, which is different from Applicants' 1,3-bis(β-hydroxyethyl) amino-2-methylbenzene, illustrated below. Specifically, Applicants' coupler has substituted amino groups meta to each other on the ring:



Nowhere in Lagrange is there a teaching of meta-phenylenediamines substituted on both amines with hydroxyalkyl. Clearly by disclosing such a specific group of meta-phenylenediamines, Lagrange did not intend to cover any others. Thus, Applicants respectfully submit that the Office's arguments on this point are misplaced and incorrect.

The Office has noted that Claussen lists couplers which would give a red color, and further has alleged that it is notoriously well known to use a wide range of couplers in the process of oxidative hair coloring in order to obtain a wide variety of colors. Final Office Action, pp. 7-8. According to the Office, however, Claussen is not applied for a teaching of how to obtain a red coloration. The Office further alleges that oxidative dyeing couplers are interchangeable absent evidence to the contrary, since they are

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used for the same purpose under the same process conditions, being added to form a wide variety of colors and nuances of color. Additionally, the Office argues that it would also have been obvious to add the claimed coupler to a composition of Claussen to modify the red coloration, since Applicants' claims do not exclude the couplers of Claussen.

However, a close reading of Clausen does not support the Office's view that it would have been obvious to use all known couplers interchangeably in the context of the Claussen invention. Rather, the invention contemplated by Clausen is directed to a narrowly disclosed inventive idea focused on solving certain particular problems in the hair dye arts. Specifically, Clausen discusses that numerous special requirements are set for oxidative dyestuffs used for coloring human hair. Requirements which are mentioned include harmless toxicological and dermatological respects, desired intensity of coloring, favorable light fastness, fastness to permanent waving, acid and rubbing fastness, and stability over a period of at least 4 to 6 weeks. See column 1, lines 21-31. Clausen further discloses that certain known developers in the red area of the color scale do not meet these special requirements, so that the problem arises of discovering an oxidative hair coloring composition based on developer substances for the red area which can better meet the aforementioned special requirements. See column 1, lines 38-48.

To address this problem, Claussen teaches a dyeing composition based on a combination of developer substances and coupler substances. See column 1, lines 48-51. Regarding the coupler substances to be used, Claussen states "[o]f the known coupler substances [various specifically named couplers] are chiefly taken into

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consideration as component part of the hair dye composition described here." See column 2, lines 18-34.

Thus, Claussen does not disclose that any known coupler may be used, but instead narrowly discloses compositions comprising named couplers as a solution for achieving the special requirements of hair dye compositions in the red area of the color scale. Given the narrow disclosure of Claussen and the specific nature of the problem being solved, it would not have been obvious to readily interchange the couplers of Claussen with other known couplers, as suggested by the Office. Nor would there necessarily have been a reasonable expectation of success of achieving the specific benefits of Claussen by substituting other known couplers, such as the 2,6-bis(2-hydroxyethylamino)-toluene disclosed by Akram, as substitutes for the couplers specifically taught by Claussen. Applicants respectfully submit that the Office's arguments amount to nothing more than obvious to try. However, as the Office is well aware, obvious to try is not sufficient to establish obviousness. See M.P.E.P. § 2145(X)(B).

The Office goes on to argue that Applicants admit that the combination of Zviak and Akram gives motivation to replace 2,6-diaminotoluene with Akram's coupler. See final Office Action, p. 8. However, Applicants merely stated, for the sake of argument only, that "at best there may" have been motivation to replace the 2,6-diaminotoluene of Zviak with Akram's coupler. See Applicants' remarks filed October 5, 2001, p. 7. This is not intended to be, nor is it, an admission that there is, in fact, motivation. And, as pointed out by Applicants' further arguments, even if there was such motivation, there

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would have been no motivation for going further and replacing the couplers of Lagrange and/or Clausen, since 2,6-diaminotoluene is not listed in Lagrange or Clausen. *Id.*

Furthermore, for the reasons discussed above with respect to the Lim and Akram combination, Zviak teaches the unpredictability of cosmetic compositions, including oxidative hair dyes. Applicants assert that the above unpredictability arguments, including the teachings of Zviak, apply equally as well to the Lagrange and/or Clausen in view of Zviak and Akram combination. Given the stringent requirements of hair dye compositions and the general unpredictability of the art, there would have been no motivation or reasonable expectation of success that replacing the 2,6-diaminotoluene of Zviak with Akram's coupler, or to go still further and replace the couplers of Lagrange and Clausen, would result in compositions having all the properties touted by *Akram*, or that they would even result in a workable hair dye.

Regarding the Office's argument that the formula III of Lagrange encompasses 2,6-diaminotoluene, Applicants respectfully disagree with the Office's conclusion that this provides a clear suggestion to form the claimed composition. The Office's rejection requires first substituting the 2,6-diaminotoluene coupler of Zviak for the couplers of Lagrange, and then substituting a second coupler, 2,6-bis(2-hydroxyethylamino)-toluene, taught by Akram, for the 2,6-diaminotoluene coupler of Zviak. Applicants respectfully submit that the Office's line of reasoning on this point is far too tenuous to support an obviousness rejection because the motivation for the double substitution required by the Office's rejection does not exist.

First of all, Lagrange teaches an extremely large number of possible couplers, none of which is Applicants' claimed coupler, as pointed out above. Lagrange does

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teach that compounds with formula (I) in dye compositions are generally used in the presence of a coupler selected from metadiphenols, metaaminophenols, and metaphenylenediamines of formula (III). See column 4, lines 43-55. However, the formula (III) which the Office relies upon to suggest 2,6-diaminotoluene contains five separate variable substituents, R₅ to R₉, each of which may be defined a number of different ways, so that formula (III) would likely encompass thousands of possible species. In addition, an extensive list of over 40 specific couplers are taught, none of which is either Applicants' claimed coupler or the 2,6-diaminotoluene, which the Office relies upon for its rejection. See, e.g., column 5, lines 10-60.

In order to supply a teaching of 2,6-diaminotoluene, the Office relies on Zviak, which provides laundry lists of various oxidation dye precursors. Zviak is a general text, and therefore provides no motivation to choose 2,6-diaminotoluene from the myriad of other couplers taught. In fact, for the reasons discussed above, Zviak provides evidence that there would have been no motivation or reasonable expectation of success for the proposed modification due to the unpredictability of the hair dye art.

Thus, neither Lagrange nor Zviak provides any direction which would suggest choosing 2,6-diaminotoluene from among the thousands of possible couplers taught in the Lagrange/Zviak combination. Given the lack of suggestion to direct the skilled artisan to 2,6-diaminotoluene, there is no motivation to go still further and substitute the 2,6-bis(2-hydroxyethylamino)-toluene taught by Akram for 2,6-diaminotoluene coupler of Zviak. Motivation must be clear and particular. See *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999). Applicants submit that no clear and particular motivation exists to make the double substitution necessary to arrive at

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Applicants' claimed invention from the proposed combination of Lagrange, Zviak and Akram, and therefore the rejection should be withdrawn.

For all the reasons set forth above, Applicants request that the art rejections of record should be withdrawn, and the present claims allowed.

III. Provisional Obviousness-Type Double Patenting Rejections

The Office has maintained the provisional rejection of claims 1-18 under the judicially created doctrine of obviousness-type double patenting over claims 1-31 of copending Application No. 09/443,142. The Office has additionally maintained the provisional obviousness-type double patenting rejection of claims 1-18 over claims 1-32 of copending Application No. 09/443,506. Solely in an effort to expedite prosecution, and in no way acquiescing in the rejection, Applicants file herewith an executed Terminal Disclaimer, thereby mooting both provisional rejections.

IV. Conclusion

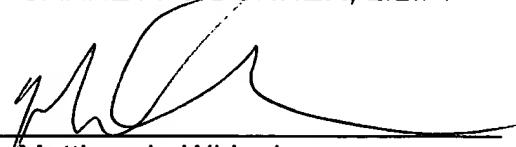
In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: April 18, 2002

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Attachment: Zviak, C., The Science of Hair Care, New York (1986) pp. 329-330.